REMARKS

Status of the claims

Claims 1-50 are pending. Claims 1-25 and 39-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Claims 26-38 are rejected. By this amendment, claims 26-38 are canceled and new claims 51-84 are added.

Support for the new claims is found in the specification and the claims as originally filed, for example: claim 51 (page 64, lines 16-18; page 17, lines 8-9; page 82, lines 1-3; page 41, lines 22-23; page 33, lines 4-6; page 38, lines 13-20; page 39, lines 29-30; page 10, lines 19-28; page 19, lines 2-5; page 48, line 19 to page 49, line 20); claim 52 (page 15, lines 5-9; page 38, lines 12-14); claim 53 (same as for claim 52); claim 54 (original claim 27; page 38, lines 12-14); claim 55 (same as for claim 54); claim 56 (page 38, lines 24-30; same as for claim 54); claim 57 (page 10, lines 25-28; page 41, lines 22-23); claim 58 (original claim 27); claim 59 (page 40, lines 16-24; original claims 31-32; page 39, lines 14-17); claim 60 (page 40, lines 16-24; page 41, lines 21-24; claim 61 (same as claim 60); claim 62 (same as claim 60); claim 63 (same as claim 57); claim 64 (page 11, lines 21-23; same as claim 60); claim 65 (page 11, lines 6-8; page 38, lines 24-28); claim 66 (page 11, lines 3-8; page 31, lines 1-9; page 38, lines 12-14; page 30, lines 21-23); claim 67 (page 38, lines 24-28; page 31, lines 1-7; page 30, lines 18-24); claim 68 (same as for claim 67); claim 69 (page 41, lines 21-24; page 19, lines 6-14; original claim 2); claim 70 (same as for claim 69; original claim 6); claim 71 (same as for claim 69; original claim 7); claim 72 (same as for claim 69; original claim 9); claim 73 (same as for claim 69; original claim 12); claim 74 (same as for claim 69; original claim 16); claim 75 (page 10, lines 25-28; page 38, lines 13-20); claim 76 (page 28, line 12, lines 13-28); claim 77 (page 1, lines 9-11; page 19, lines 2-5; Tables 4, 5, 6; page 72, lines 14-27; page 30, lines 14-27; page 31, lines 11-16; page 19, lines 15-25); claim 78 (page 29, lines 5-7); claim 79 (page 28, lines 14-25); claim 80

(page 42, lines 23-26); claim 81 (page 42, lines 28-29); claim 82 (page 46, lines 3-5); claim 83 (original claim 37); claim 84 (page 27, line 9 et seq).

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application.

Rejections under 35 U.S.C. §112, first paragraph

Claims 26, 33-35, 37 and 38

Claims 26, 33-35, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, claims 26, 33-35, 37 and 38 are rejected on the ground that the specification allegedly does not teach the nature of C-antigen, its chemical and molecular weight nor provide any guidance as how to identify or isolate the antigen so that antibodies to it may be made or identified. Applicants respectfully traverse this rejection.

Claims 26, 33-35, 37 and 38 have been canceled and new claims 51-84 have been added. Support for the new claims is listed on pages 7 and 8, above. Applicants will address this rejection in the context of the new claims.

New claims 51-84 address the Examiner's concern by defining the specificity of the antigen binding fragments recited in the claims in a manner in which the isolation of the antigen is not required. More particularly, any antibody which is empirically determined to inhibit the binding of an antibody or a fragment thereof having the amino acid sequences of the H chain V region and the L chain V region of the polypeptide shown in SEQ ID NO:14, or which has similar amino acid sequences responsible for antibody specificity (as evidence for example by

competitive inhibition, the same pattern of tumor reactivity, the same immunologic specificity, or binding to the same heptapeptide mimotope), could be made and determined to fall within the parameters specified in the claims, by methods well known in the art.

Moreover, the specification provides ample guidance on how to identify antigen binding fragments falling within the parameters specified by the claims. See, e.g., page 48, line 19 to page 49, line 20; Examples 4-9. Applicants further point out that methods for making the polynucleotides of the invention are well known in the art and also amply provided in the specification. See, e.g., page 41, lines 4-13 (describing hybridization conditions for forming a stable polynucleotide duplex); page 41, line 28- page 44, line 27 (methods of making, cloning and expressing polynucleotides); see also Example 7 (describing preparation of polynucleotides, including the polynucleotide shown in SEQ ID NO:13). Accordingly, Applicants submit that the present application fully enables the claims. Applicants note that similar claims were allowed in the parent application to the present application. See U.S. Patent No. 6,207,153. For the above-stated reasons, Applicants respectfully request withdrawal of this rejection.

Claims 37 and 38

Claims 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection.

Applicants respectfully disagree that the specification "does not provide any guidance as to the *use* of a polynucleotide sequence encoding an antibody that recognizes C antigen which is immunogenic nor does it provide any guidance as to how it is contemplated to be useful as a pharmaceutical composition", as stated by the Examiner in the rejection. Office Action, page 3. Applicants respectfully point out that the specification teaches that polynucleotides of the invention have many uses, including, for example, in a pharmaceutical composition including

vaccines and for gene therapy. See, e.g., specification, page 46, lines 25-26; see generally specification, page 46, line 20 to page 48, line 18.

However, claims 37 and 38 have been canceled. As discussed above, new claims 51-84 address the Examiner's concern with respect to, for example, how to identify or isolate the antigen, by defining the specificity of the antigen binding fragments recited in the claims in a manner in which the isolation of the antigen is not required. In addition, new claim 83 recites "[a] composition comprising a polynucleotide according to any one of claims 51-81". As noted above, the specification teaches that polynucleotides of the invention have many uses, including in expression systems for the production of the polypeptides of the invention. See, e.g., specification, page 46, line 20- page 48, line 18. For the above-stated reasons, Applicants respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. §112, second paragraph

Claims 26-38 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

As a preliminary matter, Applicants respectfully point out that while the Examiner states that she has rejected claims 26-38 under Section 112, second paragraph, the Examiner has provided reasons for only the rejection of claims 28, 29, 30, 32, and 36. Applicants assume that the Examiner intended to reject only claims 28, 29, 30, 32, and 36, and that the stated rejection of claims 26-38 was a typographical error. Applicants would appreciate clarification from the Examiner if this is not the case.

A. Claims 28 and 29 are objected to under 37 CRF 1.75 (c), as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim.[1]

[1] Applicants respectfully note for the record that an objection under 37 CFR Section 1.75 (c) is not a statutory ground for rejection. As such, the inclusion of this objection under a statutory ground of rejection, ie 35 USC Section 112, second paragraph, is improper.

Claims 28 and 29 have been canceled, thus mooting this rejection. Applicants respectfully request withdrawal of this objection.

B. Claims 28 and 29 allegedly lack antecedent basis in the claims with respect to the recitation of "encoding sequence". Claims 28 and 29 have been canceled, thus mooting the rejection. Applicants respectfully request withdrawal of this rejection.

C. Claims 32 (28, 29, 30) and 36 are allegedly ambiguous in that the metes and bound of "stable duplex" is allegedly not clear. Applicants respectfully traverse this rejection.

Claims 28, 29, 30, 32, and 36 have been canceled. Applicants will address this rejection with respect to the rejected claims as well as new claim 61 and claims depending therefrom which recite the term "stable duplex".

Applicants respectfully submit that one skilled in the art understand the meaning of the term "stable duplex" of polynucleotides, because the term has an art-recognized meaning. Applicants further point out that the specification states that a "stable duplex" of polynucleotides "refers to a duplex or complex that is sufficiently long-lasting to persist between the formation of the duplex or complex and subsequent detection, including any optional washing steps or other manipulations." Specification, page 22, lines 1-5. Applicants also note that the specification describes exemplary hybridization conditions for the formation of a stable duplex. See, e.g., specification, page 41, lines 4-13; see also, specification, page 46, line 27- page 5. Accordingly, Applicants respectfully submit that the scope of the term "stable duplex" is clear. Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In the unlikely event that the Fee Transmittal is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this

document to **Deposit Account No. 03-1952** referencing docket no. 316082000121. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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